

REMARKS

This is in response to the Office Action dated March 17, 2006 rejecting original claims 28-49. Claim 33 is presently amended. Claims 28-49 are thus pending. It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims under examination be allowed.

Examiner Interview

Applicants wish to acknowledge with appreciation the courtesies extended by the Examiner during the Examiner Interview on May 3, 2006. The Examiner's comments were helpful to Applicants in preparing this response.

INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge, with appreciation, the Examiner's indication that the references submitted in three Information Disclosure Statements filed April 23, 2004, February 1, 2005 and June 8, 2005 respectively have been considered.

Rejection Under 35 U.S.C. §112

Claims 34-38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Responsive to the rejection, Applicants submit that in amended form, claim 33 provides the necessary antecedent basis. Specifically, claim 33 has been amended to depend from claims 30 to 32 instead of 28 to 32. As such, adequate antecedent basis for a "balloon" in respect to claim 33 and claims depending therefrom is provided. In view of the amendment, reconsideration of the rejection is respectfully requested.

Rejection Under 35 U.S.C. §102

Claims 28, 29, 33 and 40-48 are rejected under 35 U.S.C. §102 (e) as being anticipated by U.S. Patent No. 6,405,732 to Edwards (hereinafter the '732 patent). The rejection is respectfully traversed for the reasons set forth below.

The standard for anticipation under 35 U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall*, 198 USPQ 344 (CCPA 1978).

As a preliminary matter, the Office Action states that the language of claim 28 directed toward treating mucosal tissue is “intended use” language. The Office Action goes on to state that the “intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” Applicants disagree with the Examiner’s analysis of claim 28. Claim 28 recites a system for treating mucosal tissue in an esophagus, said system comprising:

an elongated member;

an energy delivery structure deployable from the elongated member and adapted to deliver energy to at least a portion of a circumferential section of the mucosal lining of the esophagus; and

means for delivering energy through the delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer.

As such, Applicants submit that Claim 28 is a means plus function claim and not simply a system claim. The third element of claim 28 recites a means for delivering energy through the delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer. Accordingly, claim 28 is not simply a system claim including intended use language and the Examiner’s refusal to give weight to the recited function is wrong as a matter of law. This claim element must be construed to cover the

corresponding structure described in the specification and equivalents thereof. 35 U.S.C. §112, ¶ 6. In re Donaldson, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

Turning now to the rejection of claim 28 in view of the '732 patent, Applicants submit that the reference does not anticipate claim 28 since it fails to teach each and every element of claim 28 or its dependent claims. This position is supported by the following:

The '732 patent teaches a procedure for the treatment of aberrant electrical sites in the lower esophageal sphincter (LES) and stomach as a means for treating GERD using devices specifically designed to perform that function. See col. 2, lns. 24-26; col. 3, lns. 34-41.

The method described in the '732 patent involves the ablation of the nerve fibers and/or pathways leading from gastric receptors to eliminate nerve impulses going from these receptors. "[T]he ablation is done in or near the cardia and/or LES." See col. 7, lns. 13-26; col. 7, ln. 47. Using the method and devices described in the '732 patent, the lesions are located in the smooth muscle layer of the sphincter at a depth of 1-4 mm from the interior surface of the sphincter wall. See col. 17, lns. 1-4. The '732 patent teaches control of the location of the lesions by actually penetrating the LES smooth muscle using needle electrodes. See col. 13, lns. 16-33; Figures 12-17, 23, 26, 27.

Furthermore, the '732 patent describes delivering energy to nerve fibers while penetrating the smooth muscle of the LES. Specifically, the reference teaches control of the location of the lesion by using needle electrodes (capable of piercing tissue to a depth). By choosing the location of the needle electrode in the LES, and consequently, choosing the location of the lesion, the '732 patent teaches creation of a buffer zone in the smooth muscle to prevent thermal damage to the mucosa. See col. 16, lns. 33-35. The '732 patent does not discuss delivery of energy to tissue under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer and does not disclose structure designed to do so.

As mentioned above, the third element of claim 28 of the present invention includes a means for delivering energy through the delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer.

Importantly, the features of a number of structures embodying the means and performing the function recited in this element are not disclosed in the '732 patent. For example, as illustrated in FIG. 1A, such means are taught in the present application as including an energy delivery supply 36 adapted to deliver energy directly to mucosal tissue at relatively high levels of power for relatively short periods of time in order to achieve the shallow depth of treatment desired so that substantial injury to the submucosal layer is avoided and regrowth of the mucosal layer is initiated. See specification page 10, lns. 10-12. In another example, the means is taught as modified electrode patterns such as shown in FIGS. 7A-D, that can improve the evenness and shallowness of lesions. See specification page 15, lns. 10-12.

Accordingly, the devices disclosed in the '732 patent fail to perform the function recited by this element of claim 28 and are neither the same nor equivalent to this element of the claimed invention. As such the '732 patent does cannot anticipate claim 28.

For the foregoing reasons, Applicants respectfully request that the rejection of claim 28 be withdrawn. Because the rejected claims dependent from claim 28 (claims 29, 33 and 40-48) include further limitations in addition to those recited in claim 28, Applicants believe that all depending claims are also allowable over the cited reference of record. Reconsideration of this rejection is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 34 and 49 are rejected under 35 U.S.C. §103 (a) as being unpatentable over the '732 patent. The rejection is respectfully traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants believe the Examiner has not met his burden under § 103 for the following reasons:

Claims 34 and 49 indirectly depend from base claim 28 and therefore include each limitation recited in the base claim. As discussed above, the '732 patent does not teach each and every element of the present invention as recited in claim 28 and accordingly claims 34 and 49 are not taught or suggested by the '732 patent. Specifically, as discussed above, the present invention recites a means for delivering energy through the delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer. In contrast, the '732 patent teaches the creation of a buffer zone in the smooth muscle to prevent thermal damage to the mucosa. See col. 16, lns. 33-35. Accordingly, the '732 patent teaches away from the present invention and fails to teach or suggest each and every limitation of the present invention.

Regarding claim 34, the Office Action correctly states that the '732 patent is silent regarding specific electrode spacing dimensions, yet alleges that a spacing of "no more than 3mm" as recited in claim 34 is obvious and easily determined through routine experimentation given the '732 patent disclosure. Again, Applicants submit that the argument is without merit given that the '732 patent teaches away from treatment conditions selected to initiate regrowth of a mucosal layer. As such, the reference would not provide a skilled artisan the motivation to modify as alleged in the Office Action.

The Office Action next alleges that an "energy dosage in the range from 1 J/cm² to 50 J/cm² over a time period of less than 5 seconds", as recited in claim 49 would be obvious in light of routine experimentation. Applicants submit that the recited energy dosage is not taught or suggested by the '732 patent. While an RF power source supplying radiofrequency energy "in the range of about 400 kHz to about 10 MHz" is disclosed, no specifics regarding energy dosage ranges, let alone dosage

ranges particular to initiating regrowth of a mucosal layer, are provided in the reference. See col 11, lns. 53-55. As such, a skilled artisan would not be motivated to perform the experimentation alleged in the Office Action based on the reference.

Finally, the Office Action restates that the parameters used in the recited claims are "intended use." For the same reasons as discussed above, the present claims are not simply system claims including intended use language, but rather patentable means plus function claims. As such, the statement is moot.

In sum, each and every element of the claimed invention is not disclosed or suggested in the cited reference. As such, the criteria of a *prima facie* case of obviousness have not been met.

For the foregoing reasons, Applicants respectfully request that the rejection of claims 34 and 49 be withdrawn. Reconsideration of this rejection is respectfully requested.

Rejection Based on Nonstatutory Double Patenting

Claims 28-49 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-89 of copending application Publication No. 2004/0215235 (hereinafter the '235 application), over claims 1-96 of copending application Publication No. 2004/0087936 (hereinafter the '936 application) and additionally over claims 1-46 of copending application Publication No. 2005/0171524 (hereinafter the '524 application). The Office Action baldly states that the conflicting claims are not identical and that "they are not patentably distinct from each other because [each] application[] claim[s] expandable energy delivery catheters used in the esophagus." Applicants respectfully submit that the Examiner has not met his burden of analysis for an obviousness-type double patenting rejection. This position is supported by the following:

MPEP 804 II.B.1. states that an analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection including the factual inquiries

set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). The factual inquiries can be summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

Given the lack of such a determination, the Examiner has not met the burden of the required analysis as set forth in MPEP 804 II.B.1. Nevertheless, had the Examiner compared the subject matter of claim 28 with the claims of the references cited, differences in claim scope and content would have been evident. For example, the '235 application claims recite methods, for example, of measuring and treating tissue of a body lumen (see claims 1-57) and methods of measuring an internal lumen dimension or determining luminal wall compliance (see claims 58-73), in addition to a system for treating a body lumen including a sizing member (see claims 74-89). Significantly the scope of the referenced claims clearly differ from the present claims, particularly since they recite limitations not presently claimed and fail to recite at least one limitation of the present base claim 28, namely:

“a means for delivering energy through a delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer.”

Similarly, in the case of the '936 application, the claims recite, for example, a barrier (see claims 1-85) or separation mechanism (see claims 86-91) limitation not presently claimed and fail to recite at least the claim 28 limitation mentioned above. Analogously, in the case of the '524 application, the claims are drawn, for example, to methods and apparatuses including electrode deployment with maintained electrode density limitations which is not presently claimed. Furthermore, the claims again fail to recite at least the claim 28 limitation mentioned above.

Appln. No.: 10/754,445; Filed: January 9, 2004
Reply to Office Action of March 17, 2006

Applicants submit that the examples given represent substantial differences and the Examiner did not address them as required. As such, the rejection is inappropriate and should be withdrawn. Applicants respectfully request reconsideration of the rejection.

CONCLUSION

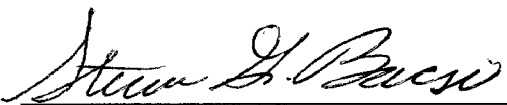
For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims under examination in this application is earnestly solicited.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 28791-702.502).

Respectfully submitted,

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Dated: June 19, 2006

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